## REMARKS/ARGUMENTS

### Pending Claims

Applicant respectfully notes that the pending claims in this case are claims 25-46, as filed with the Preliminary Amendment dated February 19, 2002. A copy of the Preliminary Amendment, as filed, is enclosed. The specification was also amended at that time to recite all of the continuing and priority information for this case.

The Preliminary Amendment was filed with the rest of the papers initiating the U.S. National Phase Application corresponding to PCT/CA00/00953. The receipt of the Preliminary Amendment was acknowledged on the 371 Formalities Letter: Notification of Missing Requirements in the United States Designated/Elected Office (DO/EO/US) mailed June 4, 2004. A copy of the 371 Formalities Letter is enclosed and the notation regarding the Preliminary Amendments is highlighted. The receipt of the Preliminary Amendment is also acknowledged on the Notice of Acceptance of Application under 35 U.S.C. 371 and 37 CFR 1.495; a copy of this document is also enclosed and highlighted.

### Information Disclosure Statements

In Item 2 of the Office Action, the Examiner requests that the references cited in the PCT International Search Report be included on a form PTO-1449. Applicants respectfully note that these references have already been listed on a form PTO-1449, as the next to the last page of the Information Disclosure Statement filed on June 2, 2003. A copy of this Information Disclosure Statement and its enclosed forms PTO-1449 (substitute), -A820, and –892 are enclosed with this response for identification.

It has been the practice of other examiners in related cases to initial the forms filed in the prior cases and return them with the next office action. Neither the June 2, 2003 nor the March 30, 2004 Supplemental Information Disclosure Statement (copy enclosed) have been acknowledged and their lists of references initialed in this Office Action. Both of these Information Disclosure Statements have been received and are listed in the file history of this case on Patent Application Information Retrieval (PAIR) system. A copy of a recent print out from private PAIR is enclosed. The examiner is respectfully requested to contact the undersigned if any of the references previously filed with these Information Disclosure Statements cannot be located.

**Claim Rejections – 35 USC § 102**

Claims 1-9, 15-19 were rejected under 35 U.S.C. 102 (b) as being anticipated by Reich (US 4,973,466). These claims are no longer pending in this application; however, applicants will discuss this reference in light of the pending claims 25-46.

Ocular dressings disclosed by the Reich reference (US '466 hereinafter) are prepared by flocculating, precipitating fibronectin, fragments or its analogs to produce a water-swellable gel, which may also include albumin. It can then be molded like contact lens and cut into appropriate shapes and sizes. When the gels are inserted into lacerations, punctures and incisions, they "expand to fill in the opening between the broken tissues due to absorption of biological fluids from surrounding tissues" (Col 5, lines 52-59). **Precipitated** fibronectin **is** the dressing, as taught in US '466. In contrast, in the present application **soluble** fibronectin is incorporated into a solid dressing. The solid dressing

according to the invention then **releases almost all of** the fibronectin as **soluble** fibronectin into the wound. Claims 25 to 42 all require that the solid wound healing formulations of this application to release soluble fibronectin. The fibronectin in the Reich reference is flocculated and unlikely to be released to the delivery site.

The methods used in US '466 are opposite those used in the present application. In US '466, the fibronectin solution starts at neutral pH, and is subsequently precipitated using acid or high salts (See, for example, col. 4. line 64 to col. 5, line 8 and Example 1 of U.S. '466). While in the present application, the fibronectin aqueous solution is basic, preferable highly basic, before it is combined with an alginate salt (Claims 43-46 of the present application). The fibronectin in the present invention remains soluble before and after it is incorporated into a solid dressing; it is never flocculated or precipitated.

**Claim Rejections – 35 USC § 102/103**

Claims 1-24 were rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Beaulieu (US 5641483). Applicants represent that the solid wound formulations of the present application release an unexpected amount of fibronectin, representing a significant and novel improvement over the hydrogels and cream formulations of US 5641483. The amounts of fibronectin released by applicants' solid wound formulations are discussed in Example 6 on page 16, line 27 to page 17, line 12 of the present application[1]. The amount released from the fibronectin/calcium alginate dressing is 262% greater than the amount released from a 1% fibronectin carbomer hydrogel. The highest concentration for a fibronectin gel

disclosed in US 5641483 is 0.5% fibronectin carbomer gel, which is only half of the amount used in the hydrogel/ solid formulation comparison reported in Example 6. US 5641483 neither suggests nor teaches how to release such a large amount of fibronectin into a wound site.

## CONCLUSION

If the Examiner has any questions or suggested Examiner's amendments, she is respectfully requested to call the undersigned.

The Commissioner is hereby authorized to charge any additional fees, or to credit any overpayment, to Deposit Account No. 50-3195. A duplicate copy of this sheet is attached.

Respectfully submitted,

Date: December 6, 2004

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Enc.
1. Preliminary Amendment filed February 19, 2002
2. 371 Formalities Letter mailed June 4, 2002
3. 371 Acceptance Letter mailed November 26, 2003
4. Information Disclosure Statement filed June 2, 2003
5. Supplemental Information Disclosure Statement filed March 30, 2004
6. Patent Application Information Retrieval Record dated November 30, 2004